Atty. Dkt. No. 076518-0145

#11 MS 10/18/01

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Andrzej Kilian and David Bowtell

Title: VERTEBRATE TELOMERASE GENES AND PROTEINS AND USES THEREOF

Appl. No.: 09/502,424

Filing Date: 02/11/100

Examiner: M. Walicka

Art Unit: 1652

RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

This is in response to the Restriction Requirement mailed July 12, 2001. A Petition for a two-month extension of time with the requisite fee, to extend the time to respond to October 12, 2001, is enclosed. Should such a request or any fee be deficient or absent, consider this paragraph such a request and authorization to charge the appropriate fee under 37 C.F.R. §§1.16 to 1.18 to Account No. 19-0741.

Applicants provisionally elect Group I, claims 1-15, 27-40, 61, 65-93 and 100-107, drawn to the telomerase gene, its variants, fragments, DNA probes, primers, expression vectors and transformed host cells to produce recombinantly vertebrate telomerase and other polypeptides, with traverse.

Applicants, of course, reserve the right to file a divisional application covering the subject matter of the non-elected claims. Applicants also elect the species, a DNA sequence encoding human telomerase or its variants corresponding to SEQ ID NO: 45. Claims 1-15, 27-40, 61, 65, 67-85, 91-93, 101 102, 104, 105 and 107 of Group I are readable on the elected species.

Regarding Restriction Requirement

The Examiner classified the pending claims into ten (10) groups. Applicants respectfully traverse the restriction and request the examination of at least Groups I, II, III, IV and V together for the following reasons.

The claims of Groups I, II, III, IV and V are drawn to the inventions as follows:

Group I : DNA, expression vector and transformed host cell to produce recombinantly vertebrate telomerase;

Group II : vertebrate telomerase, its variants and fragments;

Group III : antibody specific for vertebrate telomerase and hybridoma cell for its production

Group IV : a method of diagnosing cancer using telomerase cDNA, and a pattern of expression of telomerase RNA; and

Group V : a method of determining a pattern of expression of telomerase RNA, and a method of diagnosing cancer using that pattern.

For a restriction requirement to be proper, however, the claimed invention must be either independent or distinct, and there must be a serious burden on the Examiner if a restriction is not required. *See* MPEP § 803. The Examiner asserts that inventions of Groups I, II and III are unrelated because they are independent chemical entities that require independent search of the patent and non-patent literature.

Inventions are unrelated, only "where they are not connected in design, operation, or effect under the disclosure of the particular application under consideration." MPEP §808.01, at 800-38. Accordingly, the examiner may only restrict between claims if those claims represent independent inventions, wherein the examiner must establish that there is no disclosed relationship between the restricted claims. As highlighted above, in the instant case, inventions of Groups I, II and III relate to vertebrate telomerase, as plainly set forth in the claims. Thus, these inventions are connected in their operation or effects associated with vertebrate telomerase.

Furthermore, MPEP § 803 recites that if "the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the

merits, even though it includes claims to distinct or independent inventions." Applicants contend that this is the case in the present application. When the examiner searches either the DNA or amino acid sequence, a GENEBANK or EMBL search will provide the sequence for the corresponding amino acid or DNA sequence simultaneously. Similarly, when the examiner performs a search for antibodies against a polypeptide, vertebrate telomerase, this search will result in a search of the vertebrate telomerase. Thus, there is no undue burden on the examiner to search the DNA sequence encoding vertebrate telomerase, the amino acid sequence which it encodes and the antibody binding to the vertebrate telomerase.

Moreover, with respect to restriction between claims of Groups IV and V, the examiner has not provided any reasons or evidence in support of the restriction. Rather, the examiner identified both Groups IV and V as classified in the same class and subclass, namely, class 435/subclass 6, one of the criteria which can be used to demonstrate a serious search burden. Accordingly, Applicants respectfully submit that the restriction between Groups IV and V should be withdrawn.

The examiner has not fully demonstrated that the inventions of Groups IV and V and Group I are independent or distinct and that there is a serious search burden on the examiner. As noted by the examiner, both claims of Group IV and V, which are directed to a process of using either telomerase cDNA or telomerase RNA, are related with claims of Group I as a product and a process of use.

However, the examiner has not shown that it will be a serious burden to examine the claims of Groups IV and V concurrently with the claims of Group I. Thus, Applicants believe that searching and examining all of the claims of Groups I, IV and V would not place an undue burden on the examiner. Finally, even if the restriction between Group I, and Groups IV and V is proper for purposes of initial examination, the PTO is obliged, under the doctrine set forth in *In re Ochiai*, to rejoinder of the claims of Groups IV and V upon a finding of allowability of the claims of Group I.

Accordingly, Applicants respectfully request that the examiner reconsider the restriction requirement of Groups I, II, III, IV and V, and examine all of the claims for the reasons set forth above.

Regarding Election of Species

The examiner further imposed an election of species requirement. Applicants provisionally elected herein the DNA sequence set forth in SEQ ID No. 45 for the purpose of initial examination. In this regard, Applicants note that while the examiner states that "[c]laims of Groups I, IV, V and of Group VIII are generic to plurality of disclosed patentably distinct species comprising **DNA molecules** encoding amino acid sequences of human **telomerase**...," neither generic claims nor DNA sequences encoding human telomerase were specifically identified. A proper reading of the above statement leads to the interpretation that all claims of these Groups are generic. Except for the case described in MPEP § 803.02 (Markush group) and 809.02(d) (burdensome search necessary), identification of generic claims is required for a proper action for election of species. MPEP § 809.02(a) Thus, Applicants respectfully request the examiner clarify this issue.

Conclusion

For the reasons indicated above, Applicants respectfully request that the examiner reconsider the restriction requirements of Groups I-V to examiner them together, and clarify or correct the requirement of election of species. Applicants earnestly await receipt of the initial Office Action on the merits.

Respectfully submitted,

Date October 12, 2001

By _____ 40,413

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